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09/461,308	12/15/1999	TAIZO AKIMOTO	Q56519	3646

7590

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/461,308

**Applicant(s)**

AKIMOTO, TAIZO

**Examiner**

Frank W Lu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27, 29-31, and 33-35 is/are rejected.
- 7) ☒ Claim(s) 28, 32, and 36 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Response to Amendment*

1. Applicant's response to the office action filed on April 29, 2003 has been entered. The claims pending in this application are claims 25-36. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on April 29, 2003.

### *Claim Rejections - 35 U.S.C. § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 25-27, 29-31, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee (US Patent No. 5,974,164, filed on October 16, 1995).

Chee teaches computer-aided visualization and analysis system for sequence evaluation.

As shown in Figure 13, at step 702 a reference nucleic acid sequence was marked with a fluorescent dye such as fluorescein. At step 704 a sample nucleic acid sequence was marked with a dye that, upon excitation, emitted light of a different wavelength than that of the fluorescent dye

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of the reference sequence such as rhodamine. At step 706 the labeled reference sequence and the labeled sample sequence were combined. At step 708 the sequences were fragmented. The fragmented nucleic acid sequences were then hybridized on a chip containing probes as shown at step 710. At step 712 a scanner generated image files that indicated the locations where the labeled nucleic acids bound to the chip. Since there was some overlap between the two signals, he performed corrections for prior to further analysis. After the corrections, the data files now corresponded to "reference" and "sample". Other marks (e.g., radioactive) could be used as labels as long as the two markers was distinguishable (see Figure 13, lines 54-67 of column 24, and lines 1-18 of column 25).

Regarding claim 25, claim 25 is a "means plus function" type of claim, claim 25 only requires a first detection means, second detection means, and an analyzing means wherein these means can perform their functions: (1) detecting a plurality of known different specific binding substances that are labeled with a first labeling substance and are disposed at a plurality of predetermined positions on a carrier of a test piece; (2) detecting an organism-originated substance that can bind to said specific binding substances and is labeled with a second labeling substance that differs from said first labeling substance; and (3) measuring a quantity of said organism-originated substance bound to said specific binding substance, based on the detected level of said second labeling signal and corrected for the detected level of said first labeling signal. Although Chee does not directly teach (1) detecting a plurality of known different specific binding substances that are labeled with a first labeling substance and are disposed at a plurality of predetermined positions on a carrier of a test piece; (2) detecting an organism-originated

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substance that can bind to said specific binding substances and is labeled with a second labeling substance that differs from said first labeling substance; and (3) measuring a quantity of said organism-originated substance bound to said specific binding substance, based on the detected level of said second labeling signal and corrected for the detected level of said first labeling signal, since Chee teaches to hybridize different fluorescence labeled "reference" and "sample" nucleic acids to a nucleic acid array and correct overlap hybridization signal, Chee teaches a first detection means, second detection means, and an analyzing means wherein these means have an ability to perform functions as recited in claim 25.

Regarding claims 26, 27, and 29-31, as shown above, since a first detection means, second detection means, and an analyzing means taught by Chee have an ability to perform functions as recited in claim 25 when said specific binding substance is a cDNA polynucleotide as recited in claim 26 or when said first labeling substance for said specific binding substance is a fluorescent dye as recited in claims 29-31, claims 26, 29, 30 are anticipated by Chee. Since an analyzing means taught by Chee have an ability to utilize a correction value calculated for each specific binding substance as recited in claim 27, claim 27 is anticipated by Chee.

Regarding claims 33-35, since Chee teaches that other labels (ie., radioactive) can be used as long as two markers is distinguishable, claims 33-35 are anticipated by Chee.

Therefore, Chee teaches all limitations recited in claims 25-27, 29-31, and 33-35.

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***Response to Arguments***

4. Applicant's arguments with respect to claims 25-36 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Claims 28, 32, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
July 17, 2003



Ethan Whisenant, Ph. D.  
Primary Examiner (FSA)